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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

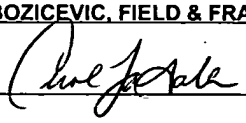
Application Number	10/055,788
Filing Date	January 16, 2002
First Named Inventor	ZHENG, XIANG YANG
Group Art Unit	1743
Examiner Name	WALLENHORST, MAUREEN
Total Number of Pages in This Submission	
Attorney Docket Number	LIFE-043

ENCLOSURES (check all that apply)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Documents
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below):*
  1) **Petition for Certificate of Correction (2 pgs.)**
  2) **Certificate of Correction (1 pg.)**
  3) **Copy of Claims from Issued Patent (2 pgs.)**
  4) **Copy of Amendment as filed on January 29, 2004**
  5) **Return Postcard**

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Signing Attorney/Agent (Reg. No.)	CAROL M. LASALLE (REG. NO. 39,740) BOZICEVIC, FIELD & FRANCIS LLP
Signature	
Date	August 6, 2004

Certificate
AUG 12 2004
of Correction

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17 AUG 2004

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PETITION FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. § 1.322 FOR PATENT AND TRADEMARK OFFICE ERROR Address to: Assistant Commissioner for Patents Washington, D.C. 20231		
	Attorney Docket Number	LIFE-043
	First Named Inventor	Xiang Yang Zheng
	Application Number	10/055,788
	Filing Date	January 16, 2002
	Patent Number	6,746,872 B2
	Issue Date	June 8, 2004
	Title	CONTROL COMPOSITIONS AND METHODS OF USE FOR COAGULATION TESTS

Sir:

Applicants petition under 37 C.F.R. § 1.322 for a Certificate of Correction to correct errors in the claims for the above-identified patent due to Patent and Trademark Office error.

Transmitted herewith for filing is a Certificate of Correction for the above-identified patent. Please make the following corrections to Claims 1, 17, 28, and 35.

In Claim 1, column 21, line 33, please remove the word "and" after the ";".

In Claim 1, column 21, line 34, please insert a -- ; -- after the word "ions" and before the word "and".

In Claim 1, column 21, line 34, please remove -- ; -- after the word "and".

In Claim 17, column 22, line 19, please replace the word "carboxylato" with the word -- carboxylate --.

In Claim 21, column 22, line 29 please insert a -- , -- after the word "ions" and before the word "hemoglobin".

In Claim 21, column 22, line 31 please insert a -- , -- after the word "ions" and before the word "hemoglobin".

In Claim 28, column 22, line 57, please remove the word "and" after the ";".

In Claim 28, column 22, line 58, please insert a -- ; -- after the word "solution" and before the word "and".

In Claim 28, column 22, line 61, please insert the word -- said -- after the word "of" and before the word "calcium".

In Claim 35, column 24, line 3 please insert a -- , -- after the word "composition" and before the word "and".

Enclosed is a copy of the Amendment filed on January 29, 2004, showing the correct form of the Claims. Also enclosed, is a copy of the last page of the issued patent showing the incorrect language of the claims that resulted from Patent and Trademark Office error.

It is believed that no fee is due since the error was made by the Patent and Trademark Office. However, the Commissioner is hereby authorized to charge any fees under 37 C.F.R. § 1.20 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 8/6/04 By: _____
Carol M. LaSalle
Registration No. 39,470

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,746,872 B2
DATED : June 8, 2004
INVENTOR(S) : Xiang Yang Zheng et al.

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In Claim 1, column 21, line 33, the word "and" after the ";" should be removed.

In Claim 1, column 21, line 34, a -- ; -- should be inserted after the word "ions" and before the word "and".

In Claim 1, column 21, line 34, the -- ; -- after the word "and" should be removed.

In Claim 17, column 22, line 19, the word "carboxylato" should be replaced with the word -- carboxylate --.

In Claim 21, column 22, line 29 a -- , -- should be inserted after the word "ions" and before the word "hemoglobin".

In Claim 21, column 22, line 31 a -- , -- should be inserted after the word "ions" and before the word "hemoglobin".

In Claim 28, column 22, line 57, the word "and" should be removed after the ";".

In Claim 28, column 22, line 58, a -- ; -- should be inserted after the word "solution" and before the word "and".

In Claim 28, column 22, line 61, the word -- said – should be inserted after the word "of" and before the word "calcium".

In Claim 35, column 24, line 3 a -- , -- should be inserted after the word "composition" and before the word "and".

MAILING ADDRESS OF SENDER:

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PATENT NO: 6,746,872 B2

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of the between day precision evaluation are shown in Table 6.

TABLE 6

	UCSF Between Day Precision		OHSU Between Day Precision	
	Level 1	Level 2	Level 1	Level 2
Mean	1.0	2.7	1.1	3.0
SD	0.092	0.201	0.083	0.226
% CV	9.1	7.4	7.2	7.7

As can be seen from Table 5 and Table 6, the %CV (coefficient of variation) using the control composition for the within run precision test was 5% or less at each investigation site. The %CV for the between day precision test for the control composition was less than 10% at each investigation site.

While the present invention has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims appended hereto.

That which is claimed is:

1. A control composition for a coagulation test, comprising:

(a) plasma aggregatable particles; and

(b calcium ions and;

(c) hemoglobin.

2. The control composition of claim **1**, further comprising at least one optical contrast enhancer.

3. The control composition of claim **1**, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

4. The control composition of claim **1**, wherein said calcium ions comprise a calcium halide.

5. The control composition of claim **1**, further comprising plasma.

6. A control composition for a coagulation test, comprising:

(a) plasma aggregatable particles;

(b) a solution of calcium ions;

(c) plasma; and

(d) hemoglobin.

7. The control composition of claim **6**, wherein said solution of calcium ions further comprises an optical contrast enhancer.

8. The control composition of claim **6**, wherein said solution of calcium ions further comprises a dissolved dye.

9. The control composition of claim **6**, wherein said particles are suspended in a solution comprising an antifreeze.

10. The control composition of claim **6**, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

11. The control composition of claim **10**, wherein said polymeric beads comprise polystyrene, and said charged functional groups comprise carboxylate groups.

12. The control composition of claim **10**, wherein said polymeric beads contain a dye.

13. A control composition for a coagulation test, comprising:

(a) a suspension of polymeric beads having charged functional groups on surfaces of said beads;

(b) a solution of calcium ions;

(c) citrated plasma; and

(d) hemoglobin.

14. The control composition of claim **13**, wherein said solution of calcium ions includes an optical contrast enhancer.

15. The control composition of claim **13**, wherein said solution of calcium ions comprises a calcium halide solution.

16. The control composition of claim **13**, wherein said polymeric beads comprise polystyrene.

17. The control composition of claim **13**, wherein said charged functional groups comprise carboxylato groups.

18. The control composition of claim **13**, wherein said polymeric beads contain a dye.

19. The control composition of claim **13**, wherein said suspension of polymeric beads further comprises an antifreeze.

20. The control composition of claim **13**, wherein said solution of calcium ion further comprises a dissolved dye.

21. A method for evaluating a coagulation test, comprising:

(a) providing a composition including calcium ions hemoglobin and plasma aggregatable particles;

(b) combining said calcium ions hemoglobin and said particles with plasma to form a control composition; and

(c) introducing said control composition and to said coagulation test.

22. The method of **21**, further comprising monitoring coagulation of said control composition.

23. The method of claim **22**, further comprising determining a coagulation time for said control composition.

24. The method of claim **23**, further comprising determining a relationship between said coagulation time of said control composition and a coagulation time of whole blood associated with said plasma in said control composition.

25. The method of claim **24**, further comprising determining a relationship between said coagulation time for said control composition, and a coagulation time using a reference test.

26. The method of claim **25**, further comprising determining a calibration curve for said coagulation test.

27. The method of claim **21**, wherein said coagulation test comprises a prothrombin time test.

28. The method of claim **21**, wherein said providing said composition comprises:

(a) providing a suspension of said particles;

(b) providing a solution of said calcium ions; and

(c) providing a hemoglobin solution and

(d) combining said suspension of said particles, said hemoglobin solution and said solution of calcium ions.

29. The method of claim **28**, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

30. The method of claim **21**, wherein providing said composition comprises including at least one optical contrast enhancer in said composition.

31. A method for evaluating a coagulation test, comprising:

(a) providing plasma aggregatable particles;

(b) providing a solution of calcium ions and a solution containing hemoglobin;

(c) combining said particles with said solution of said calcium ions and said solution containing hemoglobin;

(d) adding citrated plasma to said combined said particles and said solutions of said calcium ions and hemoglobin to form a control composition; and

(e) introducing said control composition to a coagulation test.

32. The method of claim 31, further comprising monitoring coagulation of said control composition.

33. The method of claim 32, further comprising determining a coagulation time for said control composition.

34. The method of claim 33, further comprising determining a relationship between said coagulation time of said control composition, and a coagulation time of whole blood associated with said plasma in said control composition.

35. The method of claim 34, further comprising determining a relationship between said coagulation time for said control composition and a coagulation time using a reference test.

36. The method of claim 35, further comprising determining a calibration curve for said coagulation test.

37. The method of claim 31, wherein said solution of said calcium ions comprises an aggregation enhancer.

38. The method of claim 37, wherein said aggregation enhancer comprises hemoglobin.

39. The method of claim 31, wherein said particles comprise polymeric beads with charged functional groups on surfaces thereof.

40. The method of claim 31, wherein said solution of said calcium ions comprises a calcium halide solution.

41. The method of claim 31, wherein said providing said particles comprises suspending said particles in an anti-freeze.

42. The method of claim 31, wherein said coagulation test comprises a prothrombin time test.

* * * * *

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AMENDMENT UNDER 37 C.F.R. §1.312		
Address to: Mail Stop Issue Fee Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket	LIFE-043
	Confirmation No.	7478
	First Named Inventor	Zheng, Xiang Yang
	Application Number	10/055,788
	Filing Date	January 16, 2002
	Group Art Unit	1743
	Examiner Name	M. Wallenhorst
	Title "CONTROL COMPOSITIONS AND METHODS OF USE FOR COAGULATION TESTS"	

Sir:

This amendment is responsive to the Notice of Allowance and Fees Due dated November 19, 2003.

Prior to issuance of the above-identified patent application, Applicants respectfully request entry of the amendments set forth below. Applicants submit that the amendments raise no new issues of patentability.

AMENDMENTS

IN THE CLAIMS

1. (Currently Amended) A control composition for a coagulation test, comprising:

(a) plasma aggregatable particles; ~~and~~

(b calcium ions ~~and~~; and

(c) hemoglobin.

2. (Original) The control composition of claim 1, further comprising at least one optical contrast enhancer.

3. (Cancelled)

4. (Original) The control composition of claim 1, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

5. (Previously Amended) The control composition of claim 1, wherein said calcium ions comprises a calcium halide.

6. (Original) The control composition of claim 1, further comprising plasma.

7. (Previously Amended) A control composition for a coagulation test, comprising:

(a) plasma aggregatable particles;

(b) a solution of calcium ions;

(c) plasma; and

(d) hemoglobin.

8. (Original) The control composition of claim 7, wherein said solution of calcium ions further comprises an optical contrast enhancer.

9. (Original) The control composition of claim 7, wherein said solution of calcium ions further comprises a dissolved dye.

10. (Cancelled)

11. (Original) The control composition of claim 7, wherein said particles are suspended in a solution comprising an antifreeze.

12. (Original) The control composition of claim 7, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

13. (Original) The control composition of claim 12, wherein said polymeric beads comprise polystyrene, and said charged functional groups comprise carboxylate groups.

14. (Original) The control composition of claim 12, wherein said polymeric beads contain a dye.

15. (Cancelled)

16. (Previously Amended) A control composition for a coagulation test, comprising:

(a) a suspension of polymeric beads having charged functional groups on surfaces of said beads;

(b) a solution of calcium ions;

(c) citrated plasma; and

(d) hemoglobin.

17. (Original) The control composition of claim 16, wherein said solution of calcium ions includes an optical contrast enhancer.

18. (Original) The control composition of claim 16, wherein said solution of calcium ions comprises a calcium halide solution.

19. (Cancelled)

20. (Original) The control composition of claim 16, wherein said polymeric beads comprise polystyrene.

21. (Original) The control composition of claim 16, wherein said charged functional groups comprise carboxylate groups.

22. (Original) The control composition of claim 16, wherein said polymeric beads contain a dye.

23. (Original) The control composition of claim 16, wherein said suspension of polymeric beads further comprises an antifreeze.

24. (Original) The control composition of claim 16, wherein said solution of calcium ion further comprises a dissolved dye.

25. (Previously Amended) A method for evaluating a coagulation test, comprising:

(a) providing a composition including calcium ions, hemoglobin and plasma aggregatable particles;

(b) combining said calcium ions, hemoglobin and said particles with plasma to form a control composition; and

(c) introducing said control composition to said coagulation test.

26. (Original) The method of claim 25, further comprising monitoring coagulation of said control composition.

27. (Original) The method of claim 26, further comprising determining a coagulation time for said control composition.

28. (Original) The method of claim 27, further comprising determining a relationship between said coagulation time of said control composition and a coagulation time of whole blood associated with said plasma in said control composition.

29. (Original) The method of claim 28, further comprising determining a relationship between said coagulation time for said control composition, and a coagulation time using a reference test.

30. (Original) The method of claim 29, further comprising determining a calibration curve for said coagulation test.

31. (Original) The method of claim 25, wherein said coagulation test comprises a prothrombin time test.

32. (Currently Amended) The method of claim 25, wherein said providing said composition comprises:

(a) providing a suspension of said particles;

(b) providing a solution of said calcium ions; ~~and~~

(c) providing a hemoglobin solution; and

(d) combining said suspension of said particles, said hemoglobin solution and said solution of said calcium ions.

33. (Original) The method of claim 32, wherein said particles comprise polymeric beads having charged functional groups on surfaces thereof.

34. (Original) The method of claim 25, wherein providing said composition comprises including at least one optical contrast enhancer in said composition.

35. (Previously Amended) A method for evaluating a coagulation test, comprising:

(a) providing plasma aggregatable particles;

(b) providing a solution of calcium ions and a solution containing hemoglobin;

(c) combining said particles with said solution of said calcium ions and said solution containing hemoglobin;

(d) adding citrated plasma to said combined said particles and said solutions of said calcium ions and hemoglobin to form a control composition; and

(e) introducing said control composition to a coagulation test.

36. (Previously Amended) The method of claim 35, further comprising monitoring coagulation of said control composition.

37. (Previously Amended) The method of claim 36, further comprising determining a coagulation time for said control composition.

38. (Previously Amended) The method of claim 37, further comprising determining a relationship between said coagulation time of said control composition and a coagulation time of whole blood associated with said plasma in said control composition.

39. (Previously Amended) The method of claim 38, further comprising determining a relationship between said coagulation time for said control composition, and a coagulation time using a reference test.

40. (Original) The method of claim 39, further comprising determining a calibration curve for said coagulation test.

41. (Original) The method of claim 35, wherein said solution of said calcium ions comprises an aggregation enhancer.

42. (Original) The method of claim 41, wherein said aggregation enhancer comprises hemoglobin.

43. (Original) The method of claim 35, wherein said particles comprise polymeric beads with charged functional groups on surfaces thereof.

44. (Original) The method of claim 35, wherein said solution of said calcium ions comprises a calcium halide solution.

45. (Original) The method of claim 35, wherein said providing said particles comprises suspending said particles in an antifreeze.

46. (Original) The method of claim 35, wherein said coagulation test comprises a prothrombin time test.

47.-54. (Cancelled)

REMARKS

Claims 1-2, 4-9, 11-14, 16-18, 20-46 remain pending in the application. Claims 3,10, 15, 19 and 47-54 were previously cancelled.

By this Amendment, claims 1 and 32 are being amended to correct typographical errors.

No new subject matter has been added. Accordingly, Applicants respectfully request entry of the Amendment.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-043.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 1/29/4

By: _____
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DATE: August 6, 2004 EV462737661US

THE EXPRESS MAIL NUMBER OF THE DAY IS: EV462737661US

The person taking the Express Mail to the Post Office is: Stuart McLeish

EXPRESS MAIL CERTIFICATION

Date of Deposit: **08/06/2004** I hereby certify that the below-listed papers or fees were inserted into a package addressed to: Commissioner for Patents, PO BOX 1450, Alexandria, Virginia 22313-1450 and was deposited by me with the United States Postal Service "Express Mail Post Office Addressee" service under 37 C.F.R. § 1.10 on the date indicated above.

Signature Stuart McLeish Date 8/6/04

Atty. Docket No.	Serial Number	Description	Atty.	Fee
AERX-091	10/251,898	Transmittal, Restriction Election	KYB	
UCAL-062CON2	10/773,795	IDS, SB08A, Copy of EP Communication dated 07/13/04, (1) Cited Reference	KYB	
STAN-290US1	10/794,589	Transmittal, Fee Sheet *in duplicate,* Copy of Notice to File Missing Parts, Supplemental ADS, Executed Declaration, Seqlist Certification, Paper Copy of Seqlist, (1) CD w/Seqlist in CRF	BEF	$495
UCAL-135	09/564,710	Transmittal, Petition for Certificate of Correction, Certificate of Correction, Copy of Columns 13-14 of USPN 6,756,039, Copy of Amendment 1.312 as filed 12/02/03	BEF	
TEIK-004	10/080,526	Transmittal, Fee Sheet *in duplicate,* petition for a Certificate of Correction, Certificate of Correction, (6) Pages from USPN 6,761,900, Copy of Notice of Allowance, Copy of Amendment/Response of 11/26/03	BEF	$100
UCAL-170CON8	10/146,717	Transmittal, Amendment After Final Rejection	PAB	
UCAL-170CON9	10/229,208	Transmittal, Amendment After Final Rejection	PAB	
BERK-008DIV	10/384,099	Transmittal, Restriction Election	PAB	
TGEN-001	09/471,703	Transmittal, Petition for Certificate of Correction, Certificate of Correction, Copy of Columns 13-14 of USPN 6,762,018, Copy of Amendment 1.111 as filed 07/02/03	EJB	
LIFE-043	10/055,788	Transmittal, Petition for Certificate of Correction, Certificate of Correction, Copy of Columns 21-24, Copy of Amendment as filed 01/29/04	CML	
UCAL-132CON	09/895,963	Petition for Certificate of Correction, Certificate of Correction, Copy of Amendment After Final Rejection, Copy of Columns 23-24	KYB	
STAN-238	10/358,370	Transmittal, Amendment After Final Rejection	PAB	